Complete Summary

GUIDELINE TITLE

Postoperative adjuvant chemotherapy, with or without radiotherapy, in completely resected non-small cell lung cancer: a clinical practice guideline.

BIBLIOGRAPHIC SOURCE(S)

Alam N, Shepherd FA, Darling G, Mackay JA, Ung YC, Evans WK, Lung Cancer Disease Site Group. Postoperative adjuvant chemotherapy, with or without radiotherapy, in completely resected non-small cell lung cancer: a clinical practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Dec. 17 p. (Evidence-based series; no. 7-1-2). [51 references]

GUIDELINE STATUS

This is the current release of the guideline.

The EVIDENCE-BASED SERIES report, initially the full original Guideline, over time will expand to contain new information emerging from their reviewing and updating activities.

Please visit the <u>Cancer Care Ontario Web site</u> for details on any new evidence that has emerged and implications to the guidelines.

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SCOPE

DISEASE/CONDITION(S)

Completely resected non-small cell lung cancer

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness Treatment

CLINICAL SPECIALTY

Oncology Pulmonary Medicine Radiation Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate if the use of postoperative chemotherapy, with or without radiotherapy, in patients with completely resected non-small cell lung cancer improves survival

TARGET POPULATION

Adult patients with completely resected non-small cell lung cancer

A complete resection is defined as an R0 resection.

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Surgery with chemotherapy versus without chemotherapy
- 2. Postoperative adjuvant chemotherapy
 - Platinum-based chemotherapy (excluding regimens with oral agents) (e.g., cisplatin-vinorelbine combination)
 - Postoperative platinum-based chemotherapy with radiotherapy (not recommended)
- 3. Oral agents alone or combined with other chemotherapy agents (adjuvant uracil-tegafur combination; considered but not recommended)

MAJOR OUTCOMES CONSIDERED

- Survival and disease-free survival (5-year, median, overall)
- Toxicity of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following databases were searched for evidence: MEDLINE (1966 to February 2005), EMBASE (1980 to 2005, week 13), CANCERLIT (1975 to October 2002), and the Cochrane Library (2005, issue 1). Search terms included the following subject headings: carcinoma, nonsmall cell lung, lung non small cell cancer, lung carcinogenesis, lung adenocarcinoma, lung alveolus cell carcinoma, lung squamous cell carcinoma, antineoplastic agent(s), drug therapy, chemotherapy adjuvant, cancer chemotherapy, surgery, cancer surgery, pleurectomy, and lung surgery; text words: non small cell lung, chemotherapy, drug therapy, adjuvant, surgery, surgical, resect, and postop; and publication types and study designs (practice guidelines, systematic reviews, meta-analyses, randomized controlled trials, phase III clinical trials, and major clinical studies). Abstract reports from the American Society of Clinical Oncology, the European Cancer Conference, and the European Society for Medical Oncology (2000 to 2004) and reference lists from relevant articles and review articles were hand searched.

Eligibility Criteria

Fully published reports or published abstracts of meta-analyses or randomized controlled trials comparing postoperative chemotherapy with the same treatment without chemotherapy in patients with completely resected nonsmall cell lung cancer (NSCLC) were included in this review. Data from slide presentations associated with abstract reports were included if the presentations were publicly available on meeting websites. Trials involving alkylating chemotherapy agents alone or in combination with non-platinum agents were excluded, because those agents have been shown to be detrimental to patient survival in an adjuvant setting. In addition, trials that involved immunochemotherapy, trials that did not report overall or disease-free survival, or trials that were published in a language other than English or French were not considered.

NUMBER OF SOURCE DOCUMENTS

Seven meta-analyses, thirteen trials involving intravenous chemotherapy, and twelve trials involving oral chemotherapy met the eligibility criteria for the systematic review.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Disease Site Group (DSG) agreed that recent meta-analyses and clinical trials clearly indicate a substantial survival benefit for postoperative platinum-based chemotherapy compared with surgery alone, particularly in patients with stage II or IIIA disease. In the case of stage IB disease, a clear benefit of chemotherapy has not been shown in two major published trials. Neither the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG) nor Adjuvant Navelbine International Trialist Association (ANITA) trials reported a survival benefit for chemotherapy in their sub-group analyses of stage IB patients. However, the early (unpublished) results of the Cancer and Leukemia Group B (CALGB) trial of stage IB patients showed a significant survival benefit associated with chemotherapy at four years. Based on this report and in the absence of results from the ANITA trial, the DSG initially felt that chemotherapy would be appropriate to offer in the stage IB setting. In light of the subsequent report of a lack of survival benefit in stage IB patients in the CALGB trial and the subset analyses from the other two published trials, the DSG revised its stance on the issue in August, 2006, and issued a revised recommendation that stated it was inappropriate to recommend chemotherapy for routine use in the stage IB population.

The DSG felt that chemotherapy regimens used in the three trials with the greatest survival benefit would be appropriate postoperative treatment options. Some DSG members suggested that a variety of chemotherapy regimens could reasonably be used in stage IIIA, and that cisplatin-vinorelbine may be the preferred regimen in stage II disease. However, others felt that cisplatinvinorelbine, the regimen used in the joint Canadian-United States (US) trial, should be selected as the treatment option of first choice because that trial included more disease stages, provided a longer follow-up period, and showed the largest absolute survival improvement. One of the drawbacks to a recommendation favouring the cisplatin-vinorelbine regimen used in both the NCIC-CTG and ANITA trials is that it involves a weekly administration of vinorelbine over 16 to 20 weeks, which is difficult for patients and providers alike. It is not known whether more conventional regimens such as the three-weekly administration of vinorelbine on days 1 and 8 and cisplatin on day 1 would have similar efficacy. In addition, some patients are not able to tolerate a cisplatinbased regimen. After further consideration, the DSG agreed to recommend only cisplatin-vinorelbine as an option in the adjuvant treatment of stage II and IIIA completely resected non-small cell lung cancer (NSCLC).

The DSG noted the survival improvement obtained with postoperative uraciltegafur combination (UFT) in early-stage NSCLC but also noted that, to date, the drug combination has only been tested in lung cancer patients in Japan and is not currently available in North America. Considering the potential differences in patient characteristics (including genetics) and tumour biology (different distributions of histology) between the two populations, the DSG feels that these results are not generalizable to a North American population. Therefore, a recommendation for or against the use of uracil-tegafur combination was not made at this time.

Based largely on the results of one individual patient data meta-analysis and one large randomized controlled trial (RCT), which both detected a significant survival detriment for postoperative radiotherapy compared with surgery alone, DSG practice guideline #7-1-1 recommended against the use of postoperative radiotherapy for patients with completely resected stage II NSCLC. No definitive recommendation was made for or against the use of postoperative radiotherapy in patients with completely resected stage IIIA disease. Although the evidence for or against the use of postoperative radiotherapy in combination with chemotherapy is unclear, in the opinion of the Lung DSG, combination chemoradiotherapy treatment should not be used in stage II disease. This opinion is based on the survival detriment associated with postoperative radiotherapy alone in stage II disease and the lack of a clear survival benefit for postoperative radiotherapy combined with chemotherapy when compared with postoperative radiotherapy alone. The evidence is insufficient to recommend for or against the use of postoperative radiotherapy combined with chemotherapy in stage IIIA disease.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

External Review by Ontario Clinicians

An earlier version of this practice guideline and systematic review, dated October 7, 2004, was circulated to 138 Ontario clinicians for feedback.

Feedback was obtained through a mailed survey of 138 practitioners in Ontario, including 37 medical oncologists, 24 radiation oncologists, 26 surgeons, 32 respirologists, and 19 other practitioners. The survey consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations should be approved as a practice guideline. Written comments were invited. The survey was mailed out on October 7, 2004. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Lung Disease Site Group (DSG) reviewed the results of the survey.

Practice Guidelines Coordinating Committee Approval Process

The practice guideline report was circulated to members of the Practice Guidelines Coordinating Committee for review and approval. Seven of 13 members of the Committee returned ballots. One member is a co-chair of the Lung DSG and was therefore not eligible to comment on the document. Six Committee members approved the practice guideline report as written. One member required a number of primarily editorial revisions, as well as clarification on why the results from the Japanese uracil-tegafur combination (UFT) trials may not be generalizable to North American populations. In the opinion of the DSG, the main reasons for the lack of generalizability include potential differences between the populations in patient characteristics (including genetics) and tumour biology (different distributions of histology). A statement to this effect was added to *Disease Site Group Consensus* in *Section 2* of the original guideline document.

The DSG provided notice to the Program in Evidence-based Care (PEBC) Report Approval Panel of its decision to change its recommendations for stage IB and IIIA disease. A letter of information was circulated to practitioners involved in the earlier external review of the report to inform them of the change to the recommendation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Disease Stage-Specific Recommendations

Completely Resected Stage IA Non-Small Cell Lung Cancer

- In the opinion of the Lung Disease Site Group (DSG), adjuvant chemotherapy should not routinely be used in this patient population due to their good overall survival and because the evidence for a survival benefit with adjuvant chemotherapy is uncertain.
- Postoperative radiotherapy in combination with chemotherapy should not be used.

Completely Resected Stage IB Non-Small Cell Lung Cancer

- Postoperative adjuvant platinum-based chemotherapy is not recommended for routine use in this population.
- Postoperative radiotherapy in combination with chemotherapy should not be used.

Completely Resected Stage II Non-Small Cell Lung Cancer

- Postoperative adjuvant cisplatin-based chemotherapy is recommended in this population.
- Postoperative radiotherapy in combination with chemotherapy should not be used.

- Postoperative adjuvant cisplatin-based chemotherapy is recommended in this population.
- The role of postoperative radiotherapy is unclear in this stage of disease.

Treatment Dose and Schedule

The National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG) trial achieved a statistically and clinically significant survival benefit for adjuvant chemotherapy without postoperative radiotherapy using vinorelbine (25 mg/m² weekly for 16 weeks) combined with cisplatin (50 mg/m² given on days 1 and 8) for patients with stage IB or II. Those studies that have demonstrated benefit for adjuvant chemotherapy in stage IIIA disease used similar regimens. It is unknown whether other doses and schedules of administration of these agents will produce similar benefits. One of the drawbacks to a recommendation favouring the cisplatin-vinorelbine regimen used in both the NCIC-CTG and Adjuvant Navelbine International Trialist Association (ANITA) trials is that it involves a weekly administration of vinorelbine over 16 to 20 weeks. This is difficult for patients and providers alike. It is also not known whether more convenient treatment schedules such as the three-weekly administration of vinorelbine on days 1 and 8 and cisplatin on day 1 would have similar efficacy. The Lung Disease Site Group recommends that practitioners use the regimen and schedule that has produced the best current results in a randomized trial. If this is not possible to do, the Lung Disease Site Group recommends that medical oncologists select one cisplatin-based chemotherapy regimen to use consistently for all adjuvant lung cancer therapy, as this should optimize patient safety.

Other Recommendations

- The use of adjuvant chemotherapy involving alkylating agents is not recommended as it has been found to be detrimental to survival.
- In the opinion of the Lung Disease Site Group (DSG), a recommendation for or against the use of the adjuvant uracil-tegafur combination (UFT) in a North American population is not appropriate at this time because the drug combination has only been tested in lung cancer patients in Japan and the results may not be generalizable to non-Japanese populations. UFT is currently not available in North America.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by meta-analyses and randomized controlled trials.

POTENTIAL BENEFITS

- Three large individual patient data meta-analyses and five analyses that pooled only published data, have detected a survival benefit in favour of some types of postoperative adjuvant chemotherapy.
 - In the Non-Small Cell Lung Cancer Collaborative Group (NSCLCCG) individual patient meta-analysis, an absolute survival benefit of 5% at five years was detected for adjuvant cisplatin-based chemotherapy in patients with potentially curative resections of early-stage disease (eight trials, 1,394 patients). Although not statistically significant (hazard ratio [HR], 0.87; 95% confidence interval [CI], 0.74-1.02; p=0.08), that benefit would be considered clinically significant and has been confirmed in subsequent meta-analyses. In the 1995 meta-analysis, adjuvant chemotherapy involving alkylating agents in five trials (2,145 patients) was found to be detrimental to survival, with a 5% absolute reduction in survival at five years (HR, 1.15; 95% CI, 1.04-1.27; p=0.005). No survival benefit or detriment was detected for postoperative adjuvant chemotherapy in combination with radiotherapy when compared with surgery plus postoperative radiotherapy alone (HR, 0.98; p=0.76).
 - In the Lung Adjuvant Cisplatin Evaluation (LACE) individual patient meta-analysis (five trials, 4,584 patients) an absolute survival advantage of 5.3% at five years was detected for cisplatin-based chemotherapy (HR, 0.89; 95% CI, 0.82-0.96; p=0.004). Subgroup analysis found the benefit varied by disease stage (stage IA: HR, 1.41; 95% CI, 0.96-2.09; stage IB: HR, 0.92; 95% CI, 0.78-1.10; stage II: HR, 0.83; 95% CI, 0.73-0.95; and stage III: HR, 0.83; 95% CI, 0.73-0.95).
 - In the Hamada individual patient meta-analysis (six trials, 2,003 patients with completely resected disease), a statistically significant survival benefit was associated with surgery followed by oral uraciltegafur combination (UFT) compared with surgery alone (HR, 0.74; 95% CI, 0.61-0.88; p=0.011), corresponding to an absolute increase in survival of 4.6% at five years.
- Among the 16 randomized controlled trials of postoperative adjuvant platinum-based chemotherapy, six involving more than 100 patients per treatment arm were published after the 1995 meta-analysis.
 - The largest trial (n=1,867), compared cisplatin in combination with one of etoposide, vinorelbine, vinblastine, or vindesine, to a control arm of no chemotherapy, and detected a survival advantage for chemotherapy (HR, 0.86; 95% CI, 0.76-0.98; p<0.03) for patients with stage IB, II or III disease. Radiotherapy was administered according to centre choice and the survival advantage observed was not differentially associated with the use of radiation or disease stage.
 - Two recent trials detected a statistically and clinically significant survival benefit for adjuvant cisplatin with vinorelbine compared with surgery alone. One trial administered cisplatin-vinorelbine to patients with stage IB or II disease, and found a 15% absolute benefit at five years. The second trial also administered cisplatin-vinorelbine and found an 8.6% absolute benefit at five years. That trial included

- patients with stage IB and II, as well as IIIA, and used radiotherapy according to centre choice. Radiation use was associated with increased mortality in univariate analysis (HR, 1.34; 95% CI 1.10-1.63, p = 0.003).
- One trial published in abstract form administered carboplatin-paclitaxel to 344 patients with stage IB disease and did not detect a significant difference in overall survival (HR, 0.80; 90% CI, 0.60-1.07, p=0.10), although a significant difference was found in disease-free survival (HR, 0.74; 90% CI, 0.57-0.96, p=0.027).
- The other two large trials, did not detect a statistically significant survival difference between treatments. Differences in trial characteristics (e.g., chemotherapy type, stage of disease, and use of radiotherapy) may have contributed to those conflicting results.
- There is strong evidence that UFT as a postoperative adjuvant chemotherapy improves survival in patients with stage I non-small cell lung cancer, particularly adenocarcinomas. However, nine of the 13 trials of adjuvant oral chemotherapy used UFT alone or in combination with other intravenous chemotherapy agents and included between 30 and 979 patients. All nine trials were conducted in Japan and involved primarily stage I disease (68-100% of patients). Among the five trials that compared adjuvant UFT-based combination chemotherapy with surgery alone, only one small trial detected a statistically significant survival benefit for adjuvant therapy (cisplatinvindesine-UFT, p=0.045). In addition, two trials (>100 patients per treatment arm) detected a survival benefit for adjuvant therapy only after pretreatment prognostic factors were taken into account (cisplatin-doxorubicin-UFT, p=0.044; cisplatin-vindesine-UFT, p=0.037). Among the seven trials that compared adjuvant UFT, given postoperatively for one to two years, with no UFT, four detected a statistically significant survival advantage with UFT. The largest of those four trials, involving 979 patients with stage I adenocarcinoma, detected an absolute survival benefit of 3% at five years (HR, 0.71; 95% CI, 0.52-0.98; p=0.04).

POTENTIAL HARMS

- In the one study using cisplatin-vinorelbine without postoperative radiotherapy patients experienced the following severe (grade 3 or 4) hematologic toxicities: neutropenia (73%), febrile neutropenia (7%), and anemia (7%).
- Common and severe non-hematologic toxicity associated with cisplatin-vinorelbine without postoperative radiotherapy included malaise or fatigue, 15%; nausea and vomiting, 7-10%; and anorexia, 10%. Treatment-related mortality associated with a cisplatin-vinorelbine combination regimen has been reported as 0.8% and 2%. In a quality-of-life analysis, only adverse effects associated with neurotoxicity persisted after treatment was completed.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

 Although the evidence for or against the use of postoperative radiotherapy in combination with chemotherapy is unclear, in the opinion of the Lung Cancer Disease Site Group, the combination treatment should not be used in stage I or II disease. This opinion is based on the lack of a clear survival benefit for chemoradiotherapy in comparison to radiotherapy alone, a strong survival benefit associated with chemotherapy alone in stage II disease (with uncertain evidence in the case of stage IB disease), and a survival detriment associated with radiotherapy alone. In the three trials of adjuvant chemoradiotherapy reviewed in this guideline, deaths associated with the combination treatment occurred in 2% to 9% of patients, while in the trials of adjuvant chemotherapy, chemotherapy-related deaths occurred in 0.8-2% of patients. However, the appropriateness of postoperative radiotherapy is less clear for stage IIIA disease: the two trials that included stage IIIA patients, and showed a statistically significant overall survival benefit for adjuvant chemotherapy, had methodological limitations in that they administered sequential radiotherapy according to centre choice.

- Insufficient evidence exists to identify specific subgroups of patients that may differentially benefit from the use of postoperative adjuvant platinum-based chemotherapy. Most adjuvant platinum-based chemotherapy trials have mainly involved patients with a good performance status (0-1) and included patients with a mix of disease stages (I-III); the only trial without postoperative radiotherapy that yielded an overall survival advantage only included patients with stage IB and stage II disease. In the two trials that administered postoperative radiotherapy according to centre choice and showed a statistically significant overall survival benefit for adjuvant chemotherapy, the survival benefit appeared to be greatest for stage IIIA patients from a forest plot of hazard ratios by disease stage and a comparison of survival curves by disease stage. However, no statistical analyses were reported by disease stage in either trial.
- The potential benefits, limitations, and toxicity of treatment should be fully discussed with the patient. Severe toxicities (grade 3 or 4) frequently associated with platinum-based chemotherapy include hematologic events, particularly neutropenia, nausea and vomiting, and fatigue. The Lung Disease Site Group believes that for stage II and IIIA disease, and for patients fit enough to receive chemotherapy, the survival benefits of adjuvant chemotherapy strongly outweigh the treatment toxicity.
- Care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult the evidence-based series is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or guarantees of any kind whatsoever regarding their content or use or application and disclaims any responsibility for their application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources

Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Alam N, Shepherd FA, Darling G, Mackay JA, Ung YC, Evans WK, Lung Cancer Disease Site Group. Postoperative adjuvant chemotherapy, with or without radiotherapy, in completely resected non-small cell lung cancer: a clinical practice guideline. Toronto (ON): Cancer Care Ontario (CCO); 2006 Dec. 17 p. (Evidence-based series; no. 7-1-2). [51 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Apr (revised 2006 Dec)

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Program in Evidence-based Care (PEBC) is a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Provincial Lung Cancer Disease Site Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

For a current list of past and present members, please see the <u>Cancer Care</u> Ontario Web site.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

One author (Dr Frances A. Shepherd) was a principal investigator of the National Cancer Institute of Canada Clinical Trials Group trial, one author accrued patients to that trial (Dr Gail Darling), and two authors (Dr Frances A. Shepherd and Dr William K. Evans) were investigators for an earlier trial reported in the review.

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Cancer</u> Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Postoperative adjuvant chemotherapy, with or without radiotherapy, in completely resected non-small cell lung cancer: a clinical practice guideline summary. Toronto (ON): Cancer Care Ontario (CCO), 2006 Dec. Various p. (Practice guideline; no. 7-1-2). Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.
- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

The following is available:

 Understanding lung cancer: A guide for patients and their families. Toronto (ON): Cancer Care Ontario (CCO), 2004 Sept. 35 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>Cancer Care Ontario</u> Web site

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NGC STATUS

This summary was completed by ECRI Institute on May 29, 2007. The information was verified by the guideline developer on June 22, 2007.

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